



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2013-0152; FRL-9390-8]

Registration Review; Draft Human Health and Ecological Risk Assessments; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of EPA's draft human health and ecological risk assessments for the registration review of acetaminophen, clofentazine, fluazinam, hexythiazox, quinclorac, sulfur, and triflumizole and opens a public comment period on these documents. Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, the pesticide can perform its intended function without unreasonable adverse effects on human health or the environment. As part of the registration review process, the Agency has completed comprehensive draft risk assessments for each of the subject chemicals and is making them available for public comment. After reviewing comments received during the public comment period, EPA will issue revised risk assessments, if appropriate, explain any changes to the draft risk assessments, and respond to comments and may request public input on risk mitigation before completing a proposed registration review decision for each of the chemicals. Through this program, EPA is ensuring that each pesticide's registration is based on current scientific and other knowledge, including its effects on human health and the environment.

DATES: Comments must be received on or before [*insert date 60 days after date of publication in the Federal Register*].

ADDRESSES: Submit your comments, identified by docket identification (ID) number for the specific pesticide of interest provided in Table 1. in Unit III., by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For information about a particular pesticide included in this document, contact:* The Chemical Review Manager identified in Table 1. in Unit III. for the pesticide of interest.

For general questions on the registration review program, contact: Jane Robbins, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-0048; fax number: (703) 305-8005; email address: robbins.jane@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, farm worker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the Chemical Review Manager identified in Table 1. in Unit III. for the pesticide of interest.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through [regulations.gov](http://www.regulations.gov) or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- vi. Provide specific examples to illustrate your concerns and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified.

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. Authority

EPA is conducting its registration review of the pesticides identified in this document pursuant to section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the procedural regulations for registration review at 40 CFR part 155, subpart C. Section 3(g) of FIFRA provides, among other things, that the registrations of pesticides are to be reviewed every 15 years. Under FIFRA, a pesticide product may be registered or remain registered only if it meets the statutory standard for registration given in FIFRA section 3(c)(5). When used in accordance with widespread and commonly recognized practice, the pesticide product must perform its intended function without unreasonable adverse effects on the environment; that is, without any unreasonable risk to man or the environment, or a human dietary risk from residues that result from the use of a pesticide in or on food.

III. Registration Reviews

As directed by FIFRA section 3(g), EPA is reviewing the pesticide registrations for acetaminophen, clofentezine, fluazinam, hexythiazox, quinclorac, sulfur, and triflumizole to ensure that they continue to satisfy the FIFRA standard for registration--that is, that these pesticides can still be used without unreasonable adverse effects on human health or the environment.

At this stage in the registration review process, consistent with the final paper, announced in the **Federal Register** issue of March 27, 2013 (78 FR 18585) (FRL-9382-5), jointly developed with the U.S. Department of Agriculture (USDA), the National Marine Fisheries Service, and the U.S. Fish and Wildlife Service (“the Services”) to enhance opportunities for stakeholder input during pesticide registration reviews and endangered species consultations, draft environmental risk assessments include an evaluation of the potential risks to federally listed endangered and threatened species (hereafter referred to as “listed species”). EPA intends to complete a refined assessment of potential risks to individual listed species, as needed. The refined listed species assessments will be based on the recommendations of the National Research Council

(NRC), which was tasked with providing advice on ecological risk assessment tools and scientific approaches in developing listed species risk assessments that are compliant with both FIFRA and the Endangered Species Act (ESA). The NRC report, issued April 30, 2013, provides recommendations to ensure scientific soundness and maximize the utility of risk assessment refinements for listed species. Additional information can be found at the following website:

<http://www8.nationalacademies.org/cp/projectview.aspx?key=49396>. Revisions to risk assessments will likely reflect Agency review of the report and any associated methodology and science policy based on the report's recommendations. Refinements to the listed species assessments may include, but not be limited to, the following:

- More detailed, species-specific ecological and biological data.
- More detailed and accurate information on chemical use patterns.
- Sub-county level spatial proximity data depicting the co-occurrence of potential effects areas and listed species and any designated critical habitat.

In the event that a draft risk assessment shows risks of concern to human health or the environment for a specific chemical, EPA reserves the right to initiate mitigation at this stage of registration review. This effort to mitigate a chemical's risks early in the registration review process is consistent with the Agency's approach for registration review. Where risks are identified early in the registration review process and opportunities for early mitigation exist, the Agency may pursue those opportunities as they arise, rather than waiting for completion of a chemical's registration review in order to mitigate risks. The public comment period for the draft risk assessments allows members of the public to provide comments and suggestions for revising the draft risk assessments and for reducing risks.

Pursuant to 40 CFR 155.53(c), EPA is providing an opportunity, through this notice of availability, for interested parties to provide comments and input concerning the Agency's draft human health and ecological risk assessments for acetaminophen, clofentezine, fluazinam, hexythiazox, quinclorac, sulfur, and triflumizole. Such comments and input could address, among other things, the Agency's risk assessment methodologies and assumptions, as applied in these draft risk assessments. The Agency will consider all comments received during the public comment period and make changes, as appropriate, to the draft human health and ecological risk assessments. EPA will then issue revised risk assessments, if appropriate, explain any changes to the draft risk assessment, and respond to comments. In the **Federal Register** notice announcing the availability of the revised risk assessments, if the revised risk assessments indicate risks of concern, the Agency may provide a comment period for the public to submit suggestions for mitigating the risks identified in those revised risk assessments before developing proposed registration review decisions on acetaminophen, clofentezine, fluazinam, hexythiazox, quinclorac, sulfur, and triflumizole. At present, EPA is releasing registration review draft risk assessments for the pesticide cases identified in the following table and further described in this unit.

Table 1.--Registration Review Draft Risk Assessments

Registration Review Case Name and Number	Pesticide Docket Identification (ID) Number	Chemical Review Manager, Telephone Number, and Email Address
Acetaminophen, Case No.	EPA-HQ-OPP-2012-	Bonnie Adler

7610	0145	(703) 308-8523 <i>adler.bonnie@epa.gov</i>
Clofentezine, Case No. 7602	EPA-HQ-OPP-2006-0240	Wilhelmena Livingston (703) 308-8025 <i>livingston.wilhelmena@epa.gov</i>
Fluazinam, Case No. 7013	EPA-HQ-OPP-2009-0039	Steven Snyderman (703) 347-0249 <i>snyderman.steven@epa.gov</i>
Hexythiazox, Case No. 7404	EPA-HQ-OPP-2006-0114	Molly Clayton (703) 603-0522 <i>clayton.molly@epa.gov</i>
Quinclorac, Case No. 7222	EPA-HQ-OPP-2007-1135	Wilhelmena Livingston (703) 308-8025 <i>livingston.wilhelmena@epa.gov</i>
Sulfur, Case No. 0031	EPA-HQ-OPP-2008-0176	Jose Gayoso (703) 347-8652 <i>gayoso.jose@epa.gov</i>
Triflumizole, Case No. 7003	EPA-HQ-OPP-2006-0115	Steven Snyderman (703) 347-0249 <i>snyderman.steven@epa.gov</i>

• *Acetaminophen*. The registration review docket for acetaminophen (EPA-HQ-OPP-2012-0145) opened in the **Federal Register** issue of March 28, 2012 (77 FR 18810) (FRL-9342-1). Acetaminophen (also known by the brand name Tylenol) is registered for use as a vertebrate pesticide to control the invasive brown tree snake in Guam. The snakes ingest baited mice, which are lethal to the snake. One FIFRA section 3 product is registered, and two FIFRA section 18 registrations are held by USDA Animal Plant Health Inspection Service. The Agency has conducted a quantitative ecological risk and endangered species assessment for acetaminophen based on the available information and on the limited use of this pesticide active ingredient. There was no need for a human health risk assessment due to acetaminophen's well-studied pharmaceutical use and extremely limited opportunities for exposure from its pesticidal use on Guam. In addition, EPA has determined that no new data are needed to support the registration review decision for acetaminophen.

• *Clofentezine*. The registration review docket for clofentezine (EPA-HQ-OPP-2006-0240) opened in the **Federal Register** issue of March 28, 2007 (72 FR 14548) (FRL-8118-3). Clofentezine is an acaricide that is currently registered as a liquid formulation for use on almonds, apples, apricots, cherries, Christmas trees, grapes, nectarines, ornamentals (greenhouse and outdoor), peaches, pears, persimmons, and walnuts. There are currently no residential uses associated with clofentezine. The Agency has conducted a human health risk assessment for both dietary (food and drinking water) and occupational exposure pathways. The Agency has also conducted a quantitative ecological risk assessment, which includes a screening-level listed species assessment. EPA acknowledges that further refinements to the listed species assessment

will be completed in future revisions and requests public comment on specific areas that will reduce the uncertainties associated with the characterization of risk to listed species identified in the current assessment.

- *Fluazinam*. The registration review docket for fluazinam (EPA-HQ-OPP-2009-0039) opened in the **Federal Register** issue of September 23, 2009 (74 FR 48559) (FRL-8434-6). Fluazinam is a pyridine fungicide registered for agricultural use on a variety of crops, including but not limited to melons, peanuts, peppers/eggplants, potatoes, and soybeans. Fluazinam is also registered for non-agricultural use on golf course turf. The Agency has conducted a human health risk assessment for dietary (food and drinking water), residential and occupational exposure pathways. An addendum to the most recent human health risk assessment was completed to incorporate information received shortly after the completion of the risk assessment. The addendum and risk assessment are available in the registration review docket. The Agency has also conducted a quantitative ecological risk assessment, which includes a screening-level listed species assessment. EPA acknowledges that further refinements to the listed species assessment will be completed in future revisions and requests public comment on specific areas that will reduce the uncertainties associated with the characterization of risk to listed species identified in the current assessment.

- *Hexythiazox*. The registration review docket for hexythiazox (EPA-HQ-OPP-2006-0114) opened in the **Federal Register** issue of February 2, 2007 (72 FR 5050) (FRL-8113-1). Hexythiazox is an acaricide that acts primarily as a mite growth inhibitor/ovicide and is used to control mites. It is registered for use on a variety of agricultural crops, turf, and various residential plants. The Agency has conducted a human health risk assessment for dietary (food and drinking water), residential, and occupational exposure pathways. The Agency has conducted a quantitative ecological risk assessment, which includes a screening-level listed species assessment. EPA acknowledges that further refinements to the listed species assessment will be completed in future revisions and requests public comment on specific areas that will reduce the uncertainties associated with the characterization of risk to listed species identified in the current assessment.

- *Quinclorac*. The registration review docket for quinclorac (EPA-HQ-OPP-2007-1135) opened in the **Federal Register** issue of December 19, 2007 (72 FR 71893) (FRL-8342-9). Quinclorac is an herbicide for the selective post-emergent control of various annual grasses and broadleaf weeds. The variety of end-use products containing quinclorac are currently registered on rice, sorghum, and wheat. Additionally, quinclorac is registered for use by commercial applicators and homeowners on lawns, parks, in and around ornamentals, and golf courses. The Agency has conducted a human health risk assessment for dietary (food and drinking water), residential, and occupational exposure pathways in support of registration review, and for new proposed use on rhubarb, and low growing berry (except for strawberry), subgroup 13-07H. The Agency has conducted a quantitative ecological risk assessment, which includes a screening-level listed species assessment. EPA acknowledges that further refinements to the listed species assessment will be completed in future revisions and requests public comment on specific areas that will reduce the uncertainties associated with the characterization of risk to listed species identified in the current assessment.

- *Sulfur*. The registration review docket for sulfur (EPA-HQ-OPP-2008-0176) opened in the **Federal Register** issue of March 26, 2008 (73 FR 16011) (FRL-8356-4). Elemental sulfur is a naturally occurring component of the earth's core and crust and is ubiquitous in the environment. Sulfur has been used as a pesticide in the United States since the 1920s, and is currently registered for use as an insecticide and fungicide on a wide range of field and greenhouse-grown food and feed crops, livestock (and livestock quarters), and indoor and outdoor residential sites. Use sites include berries, field crops, ornamentals, pets (dogs), root crops, tree fruit, vegetables, and turf (including residential lawns and golf courses). Sulfur is also registered for use in gas cartridge products, which are used for vertebrate pest control in a variety of sites. The Agency has conducted a qualitative human health risk assessment. The Agency has also conducted a quantitative ecological risk assessment, which includes a screening-level listed species assessment. EPA acknowledges that further refinements to the listed species assessment will be completed in future revisions and requests public comment on specific areas that will reduce the uncertainties associated with the characterization of risk to listed species identified in the current assessment. The human health risk assessment includes all uses of sulfur, including gas cartridges. The most recent ecological risk assessment includes all uses except gas cartridges. A separate ecological risk assessment for gas cartridge uses was conducted in 2010 and can be found in the sulfur registration review docket.

- *Triflumizole*. The registration review docket for triflumizole (EPA-HQ-OPP-2006-0115) opened in the **Federal Register** issue of March 28, 2007 (72 FR 14548) (FRL-8118-3). Triflumizole is a broad spectrum, imidazole fungicide (group 3) that inhibits ergosterol biosynthesis in fungi. It is registered for use on a variety of agricultural crops, ornamentals in greenhouses/shade houses, interior scapes, and Christmas trees/conifers on nurseries and plantations. It is also registered for use as a pre-plant pineapple seed treatment. The Agency has conducted a human health risk assessment for dietary (food and drinking water), residential and occupational exposure pathways. The Agency has also conducted a quantitative ecological risk assessment, which includes a screening-level listed species assessment. EPA acknowledges that further refinements to the listed species assessment will be completed in future revisions and requests public comment on specific areas that will reduce the uncertainties associated with the characterization of risk to listed species identified in the current assessment.

1. *Other related information*. Additional information on these pesticides is available on the chemical pages for these pesticides in Chemical Search, <http://www.epa.gov/pesticides/chemicalsearch>, and in each chemical's individual docket listed in Table 1. in Unit III. Information on the Agency's registration review program and its implementing regulation is available at http://www.epa.gov/oppsrrd1/registration_review.

2. *Information submission requirements*. Anyone may submit data or information in response to this document. To be considered during a pesticide's registration review, the submitted data or information must meet the following requirements:

- To ensure that EPA will consider data or information submitted, interested persons must submit the data or information during the comment period. The Agency may, at its discretion, consider data or information submitted at a later date.

- The data or information submitted must be presented in a legible and useable form. For example, an English translation must accompany any material that is not in English and a written transcript must accompany any information submitted as an audiographic or videographic record. Written material may be submitted in paper or electronic form.

- Submitters must clearly identify the source of any submitted data or information.

- Submitters may request the Agency to reconsider data or information that the Agency rejected in a previous review. However, submitters must explain why they believe the Agency should reconsider the data or information in the pesticide's registration review.

As provided in 40 CFR 155.58, the registration review docket for each pesticide case will remain publicly accessible through the duration of the registration review process; that is, until all actions required in the final decision on the registration review case have been completed.

List of Subjects

Environmental protection, Acetaminophen, Clofentezine, Fluazinam, Hexythiazox, Pesticides and pests, Quinclorac, Sulfur, Triflumizole.

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